

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA**

In re: Genentech, Inc., Herceptin
(Trastuzumab) Marketing and Sales
Practices Litigation

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MDL Docket No. 16-MD-2700

Document Relates to:
All Cases

**PLAINTIFFS' MOTION TO COMPEL NON-PARTY
PATHEON MANUFACTURING SERVICES, LLC TO
COMPLY WITH SUBPOENA DUCES TECUM**

Plaintiffs seek an Order compelling third-party Patheon Manufacturing Services LLC (“Patheon”) to produce full, unredacted copies of all documents sought by the Subpoena Duces Tecum (the “Subpoena”) served by Plaintiffs on September 2, 2016. In its May 8, 2017 Order and Opinion (the “May 8 Order”), the Court ruled the Subpoena seeks relevant information and is “not overly broad or burdensome.” [Dkt. #207 at 16.] Despite this ruling, and despite Patheon’s failure to timely object to the Subpoena, Patheon has failed to produce all documents sought by the Subpoena and has produced heavily redacted versions of other documents. Patheon should be required to fully comply with the Subpoena.

PLAINTIFFS' ATTEMPTS TO MEET AND CONFER

Plaintiffs’ counsel has attempted to confer with counsel for Patheon to discuss the matters at issue in this Motion. On August 9, 2017, Plaintiffs’ counsel sent Patheon’s counsel a letter via email asking for dates and times on which the parties could confer by the end of that week. Plaintiffs’ counsel also attempted to reach Patheon’s counsel by telephone and voicemail on August 11 and 14, 2017.¹ Plaintiffs’ counsel received no response. Plaintiffs have thus “attempted to confer,” as required by Fed. R. Civ. P. 37(a)(1) and LCvR 37.1. Prior to these attempted communications, counsel for Plaintiffs and Patheon communicated several times regarding the

¹ Patheon’s counsel is located in Newark, New Jersey, so the “distance between counsels’ offices renders a personal conference infeasible.” LCvR37.1

Subpoena, and Patheon's counsel made clear that it does not intend to produce the information sought in this Motion.

BACKGROUND

On June 24, 2016, the Court entered Case Management Order #1, permitting Plaintiffs to begin discovery related to Genentech's preemption defense. [Dkt. #39 at 4.] Since that time, Plaintiffs have diligently sought discovery of relevant information. On August 26, 2016, Plaintiffs informed Magistrate Judge Wilson of Plaintiffs' intention to serve certain third-party subpoenas for the production of documents. [Dkt. #119 at 16:11-18.] Judge Wilson told Plaintiffs to "go ahead and serve those," but instructed Plaintiffs that if Genentech indicated it would move to quash the subpoenas, Plaintiffs should "notify the third parties that they shouldn't actually produce any documents until there's been a ruling from the court." [*Id.* at 17:2-6.]

On September 2, 2016, Plaintiffs served Subpoenas Duces Tecum on nine third parties, including Patheon.² Ex. 1, Patheon Subpoena. On September 6, 2016, Genentech informed Plaintiffs that "Genentech will be filing motions to quash the third-party subpoenas." Ex. 3, Sept. 6 Email. As directed by Judge Wilson, Plaintiffs immediately informed the third parties of Genentech's objection to the subpoenas and instructed them not to "produce any documents until the court has ruled on Genentech's Motion to Quash." Ex. 4, Sept. 7 Letter. In response to the follow-up letter, Plaintiffs received written objections from a few third parties. ***Plaintiffs received nothing from Patheon.*** On September 13, 2016, Genentech filed its Motion for Protective Order asking the Court to "enter an order forbidding and/or limiting the third-party discovery." [Dkt. #124 at 1.]

On May 8, 2017, the Court entered a sealed order denying Genentech's Motion. [Dkt. #207.] The Court limited one of the categories of documents sought by Plaintiff, but otherwise found that Plaintiffs' requests to Patheon were "not overly broad or burdensome." [*Id.* at 15-16.]

² Plaintiffs also served a subpoena on Patheon Pharmaceuticals Services Inc., but counsel for Patheon has informed Plaintiffs that "Patheon Pharmaceuticals Services Inc. is not a proper third-party," as it "has nothing to do with manufacturing the product at issue." *See* Ex. 2, June 26 Letter.

On May 16, the Court unsealed its May 8 Order. The next day, on May 17, Plaintiffs sent a letter to Patheon and the other subpoena recipients informing them of the Court's ruling and asking that they contact Plaintiffs' counsel to "make arrangements to produce the responsive documents" by June 10. Ex. 5, May 17 Letter.³

As of June 10, 2017, Patheon had not responded to Plaintiffs. So, Plaintiffs found a contact number for an in-house attorney associated with one of the Patheon entities. Although the in-house attorney never responded to a voicemail from Plaintiffs' counsel, Patheon's outside counsel called Plaintiffs' counsel on June 19. On June 20, counsel for Plaintiffs and Patheon participated in a phone call to discuss the Subpoena. In conjunction with the call, Plaintiffs provided Patheon with copies of the May 8 Order (Dkt. #207), the May 17 Letter (Ex. 5), Genentech's Motion for Protective Order (Dkt. #124), the comprehensive Protective Order governing this case (Dkt. #43), and the original Subpoena issued to Patheon (Ex. 1).

On the call, Patheon's counsel claimed that it had not waived its objections to the Subpoena, although Patheon had not served any objections in the ten months following its receipt of the Subpoena. Referencing Plaintiffs' September 7 Letter, Patheon argued the letter not only excused it from producing documents during the pendency of Genentech's motion for protective order but it also tolled Patheon's obligation to timely object to the Subpoena. Plaintiffs disagreed with Patheon's position and explained that Patheon waived its objections by not raising them within the 14 days allowed under Fed. R. Civ. P. 45. At no time was Patheon or any other third party instructed to stay or refrain from serving objections to the Subpoena.

On the June 20 call, Patheon's counsel informed Plaintiffs that he would be out of the office for extended travel starting June 22, returning the week of July 17. Plaintiffs' counsel told Patheon's counsel that Plaintiffs were not willing to "wait another month for you to return from your trip and then have Patheon refuse to provide us with the subpoenaed documents." Ex. 6, June

³ Because Patheon had never responded to the Subpoena, Plaintiffs had no direct contact information for Patheon and were required to send the May 17 Letter by certified mail to Patheon's registered service agent.

22 Email. On June 26, Patheon's counsel sent a letter committing to substantively "respond to [the Subpoena] the week of July 17, 2017...and at the very least produce all agreements between Patheon and Genentech that relate to Patheon's manufacture and production of the product at issue." Ex. 2. Patheon also reasserted its "position that the fourteen (14) days permitted to object to the Subpoenas began running on the date Patheon received formal notice of the Court's denial of the Motion for a Protective Order." *Id.*

On July 21, 2017, Patheon finally responded to Plaintiffs' Subpoena. Ex. 7, July 21 Letter. Patheon stated that its June 26 Letter had "reserved its rights to raise objections to the Subpoena and stated that the fourteen (14) days permitted to object to the Subpoena will begin running on the date Patheon receives formal notice of the Court's denial of the Motion for a Protective Order."⁴ *Id.* Patheon then claimed it had only received such "formal notice" on July 14, when it "received, [] by way of [its registered agent], [Plaintiffs'] May 17, 2017 letter advising that Judge Kern entered an Order denying Genentech's Motion for a Protective Order." *Id.* at 1. Relying on this disingenuous "reservation," Patheon asserted various objections and refused to produce the communications requested in the Subpoena. *Id.* at 3. Objecting to Plaintiffs' request for communications between Patheon and Genentech "about either (i) target fill weight for the harvested drug substance to be used in multi-dose vials of Herceptin, or (ii) target vial fill multi-dose vials of Herceptin," Patheon stated:

Patheon objects to this Request to the extent it seeks documents that are privileged and confidential. Patheon further objects to this Request as overly broad, unduly burdensome, vague, and ambiguous. Patheon further objects to this Request in that the information sought is available from Genentech, the defendant in the captioned litigation, and can be obtained by way of discovery from Genentech. Any and all communications from Genentech to Patheon will necessarily be in Genentech's possession and should be obtained from Genentech, the defendant in the litigation.

⁴ This flatly mischaracterizes the June 26 Letter, which stated that "the fourteen (14) days permitted to object to the Subpoenas *began* running on the date Patheon *received* formal notice of the Court's denial of the Motion for Protective Order." Ex. 2 (emphasis added). Its use of the past tense conceded that Patheon had *already received* formal notice of the Court's ruling when Plaintiffs provided Patheon's counsel with copies of the Court's May 8 Order and other relevant documents on June 20, 2017.

A third-party should not be burdened with producing what will likely amount to a vast amount of documents, i.e. *all* communications, that the plaintiff can obtain from a party to the litigation. Such an unnecessary burden upon a third-party is exactly what Rule 45 seeks to avoid.

Id. at 3.

Although Patheon produced 987 pages of documents in response to the Subpoena, it redacted large portions of those documents without any explanation. Many of the redactions were in white, making it very difficult to tell a redaction had occurred. Plaintiffs have determined that some of the redactions relate to parts of the agreements addressing specific issues relevant to this litigation, including Genentech's and Patheon's obligations when drug substance is out of specification range and how rejected or non-conforming lots are handled.

Finally, all of the pages Patheon produced in response to the Subpoena were marked "HIGHLY CONFIDENTIAL ATTORNEYS EYES ONLY," which is not permitted under the Protective Order in this case.

On August 9, Plaintiffs emailed a letter to Patheon's counsel identifying the deficiencies in Patheon's response to the Subpoena and asking for Patheon's "immediate attention to this matter." Ex. 8, Aug. 9 Letter. Plaintiffs asserted that "[t]o avoid further delay, [the parties] must confer before the end of this week to discuss the Subpoena and Patheon's responses to it." *Id.* at 2. At the time of this filing Plaintiffs have received no response.

ARGUMENT

I. This Court has jurisdiction to compel Patheon to produce documents.

This Court has the authority to compel Patheon to produce the documents at issue here. Pursuant to 28 U.S.C. § 1407(b), "coordinated or consolidated pretrial proceedings shall be conducted by a judge...to whom such actions are assigned by the judicial panel on multidistrict litigation." As the transferee court in this MDL, the Court "exercise[s] the powers of a district judge in any district" to handle pretrial matters like this Motion. Although Section 1407(b) specifically mentions pretrial depositions, "[s]everal courts have reconciled the language of both

the statute and [Fed. R. Civ. P. 45] to find that the statute's reference to 'depositions' encompasses document production subpoenas as well." *In re Asbestos Prods. Liab. Litig. (No. VI)*, 256 F.R.D. 151, 154 (E.D. Pa. 2009) (citations omitted). This interpretation is

reasonable in light of the purpose of [Section 1407] to coordinate and consolidate pretrial proceedings, providing centralized management "to ensure 'just and efficient' conduct." To hold that a court presiding over an MDL case could not enforce a motion to compel would hamper the ability of an MDL court to coordinate and consolidate pretrial proceedings.

Id.; see also *In re Subpoenas Served on Wilmer, Cutler & Pickering and Goodwin Proctor LLP*, 255 F. Supp. 2d 1, 2 (D.D.C. 2003) (declining to rule on parties' motions to quash document subpoenas because "the authority to rule on the instant motion lies with" the transferee court). This Court is the proper forum for this Motion.

II. The Court already ruled the Subpoena seeks relevant information and is "not overly broad or burdensome."

In its 17-page May 8 Order, the Court addressed not only the relevance of the documents requested in the Subpoena but also the breadth of the requests and their related burden. The Court specifically held the documents are "relevant to impossibility preemption," and that "the requests [are] not overly broad or burdensome." [Dkt. #207 at 16.] The Court should enforce its prior ruling and require Patheon to produce unredacted versions of the documents it produced on July 21, 2017. The Court should also order Patheon to produce the two limited categories of communications Plaintiffs sought in the Subpoena: "communications from Genentech, or a person or entity acting on its behalf, to Patheon [] about either (i) target fill weight for the harvested drug substance to be used in multi-dose vials of Herceptin, or (ii) target vial fill for multi-dose vials of Herceptin." Ex. 1 at Exhibit A. As the Court has already noted, this is a narrowly tailored request seeking communications to Patheon *from Genentech* related to two specific issues; it is well within the scope of permissible discovery.

III. **Patheon's objections are untimely and meritless.**

The Court should reject Patheon's objections to the Subpoena. Patheon waived those objections when it failed to raise them in a timely manner. Patheon admits its registered agent received the Subpoena on September 7, 2016. Ex. 7 at 1. Although Patheon argued that Plaintiffs' September 7, 2016 letter, which was sent at the Court's instruction, somehow "tolled" Patheon's duty to respond to the Subpoena, there is no basis for that argument. The letter did not tell Patheon to withhold or reserve its objections; it merely instructed Patheon to refrain from producing responsive documents until the Court ruled on Genentech's Motion. Ex. 4. Indeed, other third parties who received the same September 7 letter served timely objections to their subpoenas after receiving the letter. Moreover, Patheon's objections are untimely even under the artificial deadline Patheon itself concocted in its June 26, 2017 letter. Patheon did not serve its objections within 14 days of first receiving notice of the Court's May 8 Order. Instead, it waited until July 21, 2017—over a month after Plaintiffs' counsel emailed Patheon's counsel a copy of the May 8 Order and discussed the order with Patheon's counsel by telephone. Patheon has waived its objections to the Subpoena by failing to assert them in a timely manner.

Even if its objections had been timely, they would not change the outcome. Patheon offers no justification for its redactions, other than claiming the Subpoena "seeks documents that are privileged and confidential." Ex. 7. In light of the comprehensive Protective Order in place in this case, the redactions are simply not justified.⁵

The only other basis Patheon offers for its objections is that "the information sought is available from Genentech, the defendant in the captioned litigation, and can be obtained by way of discovery from Genentech." Ex. 7. Patheon's late objection is based on the assumption that

⁵ Patheon's redactions of its agreements with Genentech appear to be identical to the redactions Genentech made to the same agreements. Plaintiffs understand from conferences with Genentech's counsel that Patheon and Genentech collaborated on the redaction of those documents. *See* Pls.' Supplement to the Parties' Second Joint Submission Regarding Preemption Discovery, Dkt #237, at 10.

Genentech has the same records and information as Patheon. Plaintiffs cannot know if that is true. Plaintiffs are entitled to receive the requested document from Patheon.

Patheon could have, and should have, raised its objections in a timely manner. It did not, and the Court should not allow Patheon to re-litigate issues Plaintiffs and Genentech already litigated for nearly nine months and which have been decided by the Court. The Court should enter an order compelling Patheon to respond to the Subpoena in full.

CONCLUSION

The Court has already ruled that Plaintiffs' Subpoena seeks relevant information and is "not overly broad or burdensome." Moreover, Patheon waived any objections it might have asserted by waiting ten months to raise them. Plaintiffs ask the Court to enter an order compelling Patheon to (1) produce unredacted versions of all documents already produced and (2) provide "all communications from Genentech, or a person or entity acting on its behalf, to Patheon [] about either (i) target fill weight for the harvested drug substance to be used in multi-dose vials of Herceptin, or (ii) target vial fill for multi-dose vials of Herceptin."

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of August, 2017, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing as required in the Court's Practice and Procedure Order (MDL Doc. #6 at ¶5).

I also transmitted a paper and electronic copy of the foregoing document to the following counsel for Patheon Manufacturing Services, LLC, who has made no appearance in this case:

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